



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,629	10/19/1999	JAY M. SHORT	DIVER1260-3	4408

7590 02/04/2005

LISA A HAILE
GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/421,629

Applicant(s)

SHORT ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,49,52 and 54-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,49,52 and 54-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 21, 2005 has been entered.

The application has been amended as requested in the communication filed January 21, 2005. Accordingly, claim 53 has been canceled, and claims 48, 59, 60 and 63 have been amended.

Claims 48, 49, 52, 54-63 are pending and under consideration.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP " 602.01 and 602.02.

The oath or declaration is defective because it contains improper claimed priority information. Specifically, it claims priority to serial number 09/089,789 filed June 3, 1998, which is a CIP of serial number 09/034,724, filed March 4, 1998, which is a CIP of 08/665,565 filed June 18, 1996.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48, 49, 52, 54-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 48, 49, 52, 54-63 are directed to all possible proteins of interest isolated by a method comprising generating a cDNA or genomic library from nucleic acid derived from environmental sample. This encompasses any protein, peptide, polypeptide, enzyme known or unknown isolated from any biological source. The specification, however, does not provide a single representative species from any biological source encompassed by these claims. There is no disclosure of any particular structure or properties of the protein of interest other than that they are obtained by a general screening method. Claim 49 limits the protein of interest enzymatic activity, whereas claims 56-58 limit the protein of interest to the product of a gene cluster including polyketide synthase. As mentioned above, the specification fails to describe any

Art Unit: 1652

specific protein of interest by any structure or properties. Given this lack of description of the protein of interest as encompassed by the claims, Applicant has failed to sufficiently describe the claimed invention; in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicant was in possession of the claimed invention.

Applicant amended independent claim 48 to narrow the scope of the claimed protein of interest to those isolated from a library constructed from a plurality of species of donor organisms derived from environmental sample, and continue to argue that the specification fully describe a method of obtaining a desired protein from said library, and therefore describe the claimed invention.

Applicant's arguments filed 1/21/05 have been fully considered but they are not deemed to be persuasive. The examiner agrees with the applicant that the specification describes a method of obtaining a protein of interest, which has been exemplified in the specification. The claims, however, are not directed to a method of obtaining a protein of interest. The claims are directed to a product of the method. The specification fails to describe any product of the method by any structural, and physical or functional characteristics. Practicing the method has the potential of obtaining unlimited number of proteins of interest, none of which is described in the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48, 49, 52, 54-63 are rejected under 35 U.S.C. 102(b) as being anticipated by the commercial availability of numerous commercial enzymes such as subtilisines, lipases, protein kinases, oxidases, glucosidases, and DNA-polymerases as well as the nucleic acids sequences, proteins, peptides and enzymes known in commercial databases. The patentability of the product of a method resides in the product itself and not the method by which it is made or identified. Applicant should note that detergent composition containing enzymatic activities such as proteases, lipases, oxidases, glycosidases, and DNA-polymerases are sold in grocery stores, and specialties outlet as well as laboratory supply houses such as SIGMA and PHARMACIA provides many of the proteins of interest encompassed by the claims.

Applicant's argues linking the genomic DNA of the plurality of organisms to the obtained proteins avoids the "commercial availability of numerous commercial enzymes as set forth by the examiner. Applicant contends that he can't fathom a commercial available protein obtain by the method described in the specification.

Art Unit: 1652

Applicants' arguments filed 1/21/05 have been fully considered but they are not deemed to be persuasive. As indicated in the prior Office actions, the patentability of the product of a method resides in the product itself and not the method by which it is made or identified. The claimed protein invention is a chemical compound that is not described in the specification by any physical or chemical characteristics, and therefore can't be distinguished from a commercially available proteins and enzymes. It should be pointed out that the majority of the commercially available enzymes are isolated from organisms readily available in the environment. *Taq* DNA-polymerase is isolated from *Thermus aquaticus*, a common bacterium found in hot springs. *Bacillus subtilis*, which is the biological source of subtilisin, a protease used in laundry detergents, is a commonly found bacterium in the environment. Practicing the method described in the specification is bound to produce one of commercially available proteins.

No claim is allowed.

This is a RCE of applicant's earlier Application No. 09/421,629. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamudhy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652